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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/468,145 06/06/95 ENGEL

J Y17506/93-11

EXAMINER

HM12/0526

MINNIFIELD, N

ART UNIT

PAPER NUMBER

1645

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DATE MAILED:

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/468,145

Applicant(s)

ENGEL ET AL

Examiner  
N. M. Minnifield

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Jan 12, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 20-23 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 20-23 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Response to Amendment*

1. Applicants' Request for Reconsideration filed January 12, 2000 is acknowledged and has been entered. Claims 20-23 are now pending in the present application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 20-23 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Engel et al (5663145).

Engel et al disclose treatment of tumour diseases using a product of Cetrorelix acetate and methods of preparing the product (abstract). Engel et al disclose mixing acetic acid and cetrorelix and adding mannitol (a bulking agent); the solution is filter sterilized (col. 2). The prior art anticipates the claimed invention.

The rejection of claims 20-23 under 35 USC 102 is maintained for the reasons as set forth above. Applicant's arguments filed January 12, 2000 have been fully considered but they are not persuasive. Applicants assert that the prior art does not disclose the claimed method for preparation of a sterile cetrorelix lyophilisate with specific reaction partners and parameters and amounts.

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It is noted that column 2 of the patent (5663145) disclose the method as claimed by applicants. With regard to Applicants assertion that the prior art does not disclose specific amounts for example, it is noted that to determine optimum concentrations of reactants in within the level of ordinary skill in the art. See In re Kronig, 190 USPQ 425. Applicants have not shown that these are critical elements to the claimed novelty or unobviousness of the claimed invention.

4. It is noted that the nonstatutory double patenting rejection set forth in the previous Office Action has been withdrawn since Applicants have elected a different invention (a method of treatment) in copending Application No. 09/233468.

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
NITA MINNIFIELD  
PRIMARY EXAMINER

N. M. Minnifield

May 18, 2000